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5/12/03  
PATENT

Customer No. 22,852  
Attorney Docket No. 1142.0125-00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: )  
)  
Graham COOK et al. ) Confirmation No.: 2584  
)  
Application No.: 10/046,727 ) Group Art Unit: 1617  
)  
Filed: January 17, 2002 ) Examiner: Kim, Jennifer M.  
)  
For: TREATMENT OF SLEEP )  
DISTURBANCES )

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**RESPONSE TO RESTRICTION REQUIREMENT**

In a restriction requirement dated March 12, 2003, the Examiner required an election under 35 U.S.C. § 121 between:

Group I - Claims 1-13, drawn to a composition comprising ibuprofen and diphenhydramine to treat a pain-associated sleep disturbance, classified in class 424, subclass 464.

Group II - Claims 14-17, drawn to a method of treating a patient suffering from a sleep disturbance comprising administering the composition comprising ibuprofen and diphenhydramine, classified in class 514, subclass 557.

Group III - Claims 18-25, drawn to a method of evaluating a compound or composition for the treatment of a pain-associated sleep disturbance, classified in class 514, subclass 1+.

Applicants provisionally elect to prosecute Group I, claims 1-13, drawn to compositions comprising ibuprofen and diphenhydramine, with traverse.

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Applicants believe that this restriction requirement is improper. While the Examiner has alleged that the claims are drawn to independent and distinct inventions, the Examiner has failed to show that it would be a serious burden on the Examiner to examine the claims together. The law requires that both (1) the inventions are independent and distinct, and (2) there would be a serious burden on the Examiner if restriction was not required. M.P.E.P. § 803.01. The Examiner has focused on only the first part of this two-part test. In order to properly restrict the groups, the Examiner needs to show that there would be a serious burden in examining the claims together.

Although, Groups I and II are related as a composition comprising ibuprofen and diphenhydramine to treat a pain-associated sleep disturbance and a method of treating a patient suffering from a pain-associated sleep disturbance using the composition comprising ibuprofen and diphenhydramine, these groups could be examined with a single search because any reference describing treatment of pain-associated sleep disturbance with a composition comprising ibuprofen and diphenhydramine would also describe the composition comprising ibuprofen and diphenhydramine itself.

Additionally, Groups I and III, which are related as a composition comprising ibuprofen and diphenhydramine and a method of evaluating a composition for treatment of a pain-associated sleep disturbance, could be examined with a single search because any reference that teaches a method of evaluating a composition comprising ibuprofen and diphenhydramine for treatment of pain-associated sleep disturbance would also describe the composition comprising ibuprofen and diphenhydramine itself. Applicants further note that Groups II and III are classified in the same class 514, which would not impose a serious burden to examine them together. Therefore, Applicants

believe that Groups I, II and III are closely related and would be easy to search together.

In view of the foregoing remarks, Applicants submit that the Examiner has not established a *prima facie* case of serious burden of search. Accordingly, Applicants respectfully request that the restriction requirement be withdrawn.

Applicants submit a petition for a one-month extension of time along with the requisite fee. Applicants believe that no additional fee is required with this submission; however, if any additional fees are necessary, please charge deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
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Dated: May 12, 2003

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